K080333

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

December 24, 2007

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Mel Sharperson
Management Representative
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	ImageGrid™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number:	K012211	K052358
Manufacturer:	EFILM MEDICAL, INC	ETIAM, S.A.
Device Name:	EFILM WORKSTATION	ETIAM STAR PACS COMPONENTS
Decision Date	07/31/2001	10/05/2005
Product Code:	LLZ	LLZ
Device Classification Name:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number:	Class II - 892.2050	Class II - 892.2050

Device Description: 21 CFR 807 92(a)(4)

ImageGrid Web Viewer is a client/server software application and server that is designed to be used with the ImageGrid PACS device or as an independent service. The ImageGrid Web Viewer can query, retrieve, and display medical images that it retrieves from a DICOM SCP. The ImageGrid Web Viewer is a client/server software service that permits concurrent access to the ImageGrid PACS' medical images. ImageGrid™ can be integrated with an institutions HIS or RIS for an integrated electronic patient record.

Indications for Use: 21 CFR 807 92(a)(5)

510(k) Summary of Safety and Effectiveness

ImageGrid™ is a software device and server that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources).

ImageGrid™ is a PACS solution, including: ImageGrid Web Viewer, ImageGrid OrderEntry, ImageGrid RIS, and ImageGrid Mammography Web Viewer.

Images (including mammography) and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Technological Characteristics: 21 CFR 807 92(a)(6)

ImageGrid™ device is a product that handles digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510 (k) Pre-Market Notification for ImageGrid™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

ImageGrid™e has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2008

Candelis, Incorporated
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Incorporated
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K080333
Trade/Device Name: ImageGrid™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 31, 2008
Received: February 7, 2008

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of February 22, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

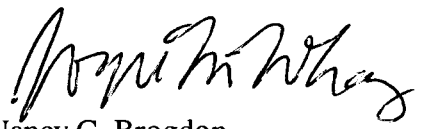
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080333

Device Name: ImageGrid™

Indications for Use:

ImageGrid™ is a software device and server that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources).

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080333